



Declaration of CE Conformity

Product Identification			
Product Name	REF	EDMS Code	Registration Date and Number
CerTest FOB (Card kit x 20 tests)	F820001F	12.70.03.21	02/06/2020 RPS/1176/2020
CerTest FOB (Card kit x 20 tests + PC)	F820001FC	12.70.03.21	02/06/2020 RPS/1176/2020
CerTest FOB (Blister kit x 40 tests)	F740001F	12.70.03.21	02/06/2020 RPS/1176/2020
CerTest FOB (Blister kit x 40 tests + PC)	F740001FC	12.70.03.21	02/06/2020 RPS/1176/2020
CerTest FOB 50+200 (Combo Card kit x 20 tests)	FB882001F	12.70.03.21	04/06/2020 RPS/1208/2020
CerTest FOB 50+200 (Combo Card kit x 20 tests + PC)	FB882001FC	12.70.03.21	04/06/2020 RPS/1208/2020
CerTest FOB+Transferrin (Combo Card kit x 20 tests)	FT882001F	12.70.03.21	04/06/2020 RPS/1208/2020
CerTest FOB+Transferrin (Combo Card kit x 20 tests + PC)	FT882001FC	12.70.03.21	04/06/2020 RPS/1208/2020
CerTest FOB-Transferrin (Blister kit x 40 tests)	FT740001F	12.70.03.21	04/06/2020 RPS/1208/2020
CerTest FOB-Transferrin (Blister kit x 40 tests + PC)	FT740001FC	12.70.03.21	04/06/2020 RPS/1208/2020
CerTest Transferrin (Card kit x 20 tests)	TF820001F	12.70.01.90	19/12/2013 RPS/967/2013
CerTest Transferrin (Card kit x 20 tests + PC)	TF820001FC	12.70.01.90	19/12/2013 RPS/967/2013
CerTest Calprotectin (Card kit x 20 tests)	CP820001F	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin (Card kit x 20 tests + PC)	CP820001FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin (Blister kit x 40 tests)	CP740001F	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin (Blister kit x 40 tests + PC)	CP740001FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin 50+200 (Combo Card kit x 20 tests)	CC882001F	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin 50+200 (Combo Card kit x 20 tests + PC)	CC882001FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Lactoferrin (Card kit x 20 tests)	LT820001F	12.70.01.90	04/06/2020 RPS/1208/2020



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CerTest Lactoferrin (Card kit x 20 tests + PC)	LT820001FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Lactoferrin (Blister kit x 40 tests)	LT740001F	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Lactoferrin (Blister kit x 40 tests + PC)	LT740001FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin+Lactoferrin (Combo Card kit x 20 tests)	CL882001F	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin+Lactoferrin (Combo Card kit x 20 tests + PC)	CL882001FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin-Lactoferrin (Blister kit x 40 tests)	CR740301F	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest Calprotectin-Lactoferrin (Blister kit x 40 tests + PC)	CR740301FC	12.70.01.90	04/06/2020 RPS/1208/2020
CerTest FOB+Transferrin+Calprotectin+Lactoferrin (Quad Card kit x 20 tests)	FC862001F	12.70.01.90	04/06/2020 RPS/1221/2020
CerTest FOB+Transferrin+Calprotectin+Lactoferrin (Quad Card kit x 20 tests + PC)	FC862001FC	12.70.01.90	04/06/2020 RPS/1221/2020
CerTest Rotavirus (Card kit x 20 tests)	R820001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus (Card kit x 20 tests + PC)	R820001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus (Blister kit x 40 tests)	R740001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus (Blister kit x 40 tests + PC)	R740001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Adenovirus (Card kit x 20 tests)	AD820001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Adenovirus (Card kit x 20 tests + PC)	AD820001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Adenovirus (Blister kit x 40 tests)	AD740001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Adenovirus (Blister kit x 40 tests + PC)	AD740001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus+Adenovirus (Combo Card kit x 20 tests)	XR882001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus+Adenovirus (Combo Card kit x 20 tests + PC)	XR882001VC	15.70.90.90	02/06/2020 RPS/1176/2020



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CerTest Rotavirus-Adenovirus (Blister kit x 40 tests)	XR740301V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus-Adenovirus (Blister kit x 40 tests + PC)	XR740301VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Astrovirus (Card kit x 20 tests)	AT820001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Astrovirus (Card kit x 20 tests + PC)	AT820001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Astrovirus (Blister kit x 40 tests)	AT740001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Astrovirus (Blister kit x 40 tests + PC)	AT740001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Rotavirus+Adenovirus+Astrovirus (Triple Card kit x 20 tests)	RT872001V	15.70.90.90	04/06/2020 RPS/1208/2020
CerTest Rotavirus+Adenovirus+Astrovirus (Triple Card kit x 20 tests + PC)	RT872001VC	15.70.90.90	04/06/2020 RPS/1208/2020
CerTest Norovirus (Card kit x 20 tests)	NN820001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Norovirus (Card kit x 20 tests + PC)	NN820001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Norovirus (Blister kit x 40 tests)	NN740001V	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Norovirus (Blister kit x 40 tests + PC)	NN740001VC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Norovirus GI+GII (Combo Card kit x 20 tests)	NV882001V	15.70.90.90	24/09/2013 RPS/872/2013
CerTest Norovirus GI+GII (Combo Card kit x 20 tests + PC)	NV882001VC	15.70.90.90	24/09/2013 RPS/872/2013
CerTest Norovirus GI-GII (Blister kit x 40 tests)	NV740301V	15.70.90.90	24/09/2013 RPS/872/2013
CerTest Norovirus GI-GII (Blister kit x 40 tests + PC)	NV740301VC	15.70.90.90	24/09/2013 RPS/872/2013
CerTest Rotavirus+Norovirus GI/GII (Combo Card kit x 20 tests)	RN882001V	15.70.90.90	24/09/2013 RPS/872/2013
CerTest Rotavirus+Norovirus GI/GII (Combo Card kit x 20 tests + PC)	RN882001VC	15.70.90.90	24/09/2013 RPS/872/2013
CerTest ROTA+ADENO+NORO (Triple Card kit x 20 tests)	RA872001V	15.70.90.90	07/02/2014 RPS/30/2014
CerTest ROTA+ADENO+NORO (Triple Card kit x 20 tests + PC)	RA872001VC	15.70.90.90	07/02/2014 RPS/30/2014
CerTest Rota+Adeno+Astro+Noro (Quad Card kit x 20 tests)	RG862001V	15.70.90.90	24/09/2013 RPS/872/2013



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CerTest Rota+Adeno+Astro+Noro (Quad Card kit x 20 tests + PC)	RG862001VC	15.70.90.90	24/09/2013 RPS/872/2013
CerTest Enterovirus (Card kit x 20 tests)	EV820001V	15.70.90.90	04/06/2020 RPS/1208/2020
CerTest Enterovirus (Card kit x 20 tests + PC)	EV820001VC	15.70.90.90	04/06/2020 RPS/1208/2020
CerTest Enterovirus (Blister kit x 40 tests)	EV740001V	15.70.90.90	04/06/2020 RPS/1208/2020
CerTest Enterovirus (Blister kit x 40 tests + PC)	EV740001VC	15.70.90.90	04/06/2020 RPS/1208/2020
CerTest H. pylori (Card kit x 20 tests)	P820001V	15.70.01.02	02/06/2020 RPS/1176/2020
CerTest H. pylori (Card kit x 20 tests + PC)	P820001VC	15.70.01.02	02/06/2020 RPS/1176/2020
CerTest H. pylori (Blister kit x 40 tests)	P740001V	15.70.01.02	02/06/2020 RPS/1176/2020
CerTest H. pylori (Blister kit x 40 tests + PC)	P740001VC	15.70.01.02	02/06/2020 RPS/1176/2020
CerTest H. pylori+Transferrin (Combo Card kit x 20 tests)	PT882001VF	15.70.01.02	04/06/2020 RPS/1208/2020
CerTest H. pylori+Transferrin (Combo Card kit x 20 tests + PC)	PT882001VFC	15.70.01.02	04/06/2020 RPS/1208/2020
CerTest Clostridium difficile antigen GDH (Card kit x 20 tests)	GD820001V	15.70.01.06	07/02/2012 RPS/114/2012
CerTest Clostridium difficile antigen GDH (Card kit x 20 tests + PC)	GD820001VC	15.70.01.06	07/02/2012 RPS/114/2012
CerTest Clostridium difficile antigen GDH (Blister kit x 40 tests)	GD740001V	15.70.01.06	07/02/2012 RPS/114/2012
CerTest Clostridium difficile antigen GDH (Blister kit x 40 tests + PC)	GD740001VC	15.70.01.06	07/02/2012 RPS/114/2012
CerTest GDH+Lactoferrin (Combo Card kit x 20 tests)	GF882001VF	15.70.01.06 & 12.70.01.90	24/05/2013 RPS/635/2013
CerTest GDH+Lactoferrin (Combo Card kit x 20 tests + PC)	GF882001VFC	15.70.01.06 & 12.70.01.90	24/05/2013 RPS/635/2013
CerTest Clostridium difficile Toxin A+B (Combo Card kit x 20 tests)	CD882001V	15.70.01.06	07/02/2012 RPS/114/2012
CerTest Clostridium difficile Toxin A+B (Combo Card kit x 20 tests + PC)	CD882001VC	15.70.01.06	07/02/2012 RPS/114/2012
CerTest Clostridium difficile Toxin A-B (Blister kit x 40 tests)	CD740301V	15.70.01.06	07/02/2012 RPS/114/2012
CerTest Clostridium difficile Toxin A-B (Blister kit x 40 tests + PC)	CD740301VC	15.70.01.06	07/02/2012 RPS/114/2012
CerTest C. difficile GDH+Toxin A+B (Triple Card kit x 20 tests)	GX872001V	15.70.01.06	20/09/2013 RPS/869/2013



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CerTest C. difficile GDH+Toxin A+B (Triple Card kit x 20 tests + PC)	GX872001VC	15.70.01.06	20/09/2013 RPS/869/2013
CerTest C. difficile GDH+Toxin A+B+Lactoferrin (Quad Card kit x 20 tests)	LX862001VF	15.70.01.06 &12.70.01.90	20/09/2013 RPS/869/2013
CerTest C. difficile GDH+Toxin A+B+Lactoferrin (Quad Card kit x 20 tests + PC)	LX862001VFC	15.70.01.06 &12.70.01.90	20/09/2013 RPS/869/2013
CerTest E. coli O157:H7 (Card kit x 20 tests)	E820001V	15.70.01.90	02/06/2020 RPS/1176/2020
CerTest E. coli O157:H7 (Card kit x 20 tests + PC)	E820001VC	15.70.01.90	02/06/2020 RPS/1176/2020
CerTest E. coli O157:H7 (Blister kit x 40 tests)	E740001V	15.70.01.90	02/06/2020 RPS/1176/2020
CerTest E. coli O157:H7 (Blister kit x 40 tests + PC)	E740001VC	15.70.01.90	02/06/2020 RPS/1176/2020
CerTest EHEC VT1+VT2 (Combo Card kit x 20 tests)	SX882001V	15.70.01.90	18/09/2013 RPS/866/2013
CerTest EHEC VT1+VT2 (Combo Card kit x 20 tests + PC)	SX882001VC	15.70.01.90	18/09/2013 RPS/866/2013
CerTest E. coli O157+ VT1+VT2 (Triple Card kit x 20 tests)	EX872001V	15.70.01.90	26/09/2013 RPS/879/2013
CerTest E. coli O157+ VT1+VT2 (Triple Card kit x 20 tests + PC)	EX872001VC	15.70.01.90	26/09/2013 RPS/879/2013
CerTest Campylobacter (Card kit x 20 tests)	CA820001V	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Campylobacter (Card kit x 20 tests + PC)	CA820001VC	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Campylobacter (Blister kit x 40 tests)	CA740001V	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Campylobacter (Blister kit x 40 tests + PC)	CA740001VC	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella (Card kit x 20 tests)	SA820001V	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella (Card kit x 20 tests + PC)	SA820001VC	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella (Blister kit x 40 tests)	SA740001V	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella (Blister kit x 40 tests + PC)	SA740001VC	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella typhi (Card kit x 20 tests)	ST820001V	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella typhi (Card kit x 20 tests + PC)	ST820001VC	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella typhi (Blister kit x 40 tests)	ST740001V	15.70.01.90	04/06/2020 RPS/1208/2020



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CerTest Salmonella typhi (Blister kit x 40 tests + PC)	ST740001VC	15.70.01.90	04/06/2020 RPS/1208/2020
CerTest Salmonella paratyphi (Card kit x 20 tests)	SP820001V	15.70.01.90	20/03/2012 RPS/227/2012
CerTest Salmonella paratyphi (Card kit x 20 tests + PC)	SP820001VC	15.70.01.90	20/03/2012 RPS/227/2012
CerTest Salmonella typhi+paratyphi (Combo Card kit x 20 tests)	TP882001V	15.70.01.90	20/03/2012 RPS/227/2012
CerTest Salmonella typhi+paratyphi (Combo Card kit x 20 tests + PC)	TP882001VC	15.70.01.90	20/03/2012 RPS/227/2012
CerTest Yersinia enterocolitica O:3 (Card kit x 20 tests)	YE820001V	15.70.01.90	24/05/2013 RPS/635/2013
CerTest Yersinia enterocolitica O:3 (Card kit x 20 tests + PC)	YE820001VC	15.70.01.90	24/05/2013 RPS/635/2013
CerTest Yersinia enterocolitica O:3 (Blister kit x 40 tests)	YE740001V	15.70.01.90	24/05/2013 RPS/635/2013
CerTest Yersinia enterocolitica O:3 (Blister kit x 40 tests + PC)	YE740001VC	15.70.01.90	24/05/2013 RPS/635/2013
CerTest Yersinia enterocolitica O:9 (Card kit x 20 tests)	YC820001V	15.70.01.90	21/03/2014 RPS/87/2014
CerTest Yersinia enterocolitica O:9 (Card kit x 20 tests + PC)	YC820001VC	15.70.01.90	21/03/2014 RPS/87/2014
CerTest Yersinia enterocolitica O:9 (Blister kit x 40 tests)	YC740001V	15.70.01.90	21/03/2014 RPS/87/2014
CerTest Yersinia enterocolitica O:9 (Blister kit x 40 tests + PC)	YC740001VC	15.70.01.90	21/03/2014 RPS/87/2014
CerTest Yersinia enterocolitica O:3+O:9 (Combo Card kit x 20 tests)	YS882001V	15.70.01.90	24/05/2013 RPS/635/2013
CerTest Yersinia enterocolitica O:3+O:9 (Combo Card kit x 20 tests + PC)	YS882001VC	15.70.01.90	24/05/2013 RPS/635/2013
CerTest Crypto (Card kit x 20 tests)	K820001V	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Crypto (Card kit x 20 tests + PC)	K820001VC	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Crypto (Blister kit x 40 tests)	K740001V	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Crypto (Blister kit x 40 tests + PC)	K740001VC	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Giardia (Card kit x 20 tests)	G820001V	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Giardia (Card kit x 20 tests + PC)	G820001VC	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Giardia (Blister kit x 40 tests)	G740001V	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Giardia (Blister kit x 40 tests + PC)	G740001VC	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Giardia+ (Card kit x 20 tests)	GW820001V	15.70.05.90	18/03/2020 RPS/343/2020
CerTest Giardia+ (Card kit x 20 tests + PC)	GW820001VC	15.70.05.90	18/03/2020 RPS/343/2020



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CerTest Giardia+ (Blister kit x 40 tests)	GW740001V	15.70.05.90	18/03/2020 RPS/343/2020
CerTest Giardia+ (Blister kit x 40 tests + PC)	GW740001VC	15.70.05.90	18/03/2020 RPS/343/2020
CerTest Crypto+Giardia (Combo Card kit x 20 tests)	NW882001V	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Crypto+Giardia (Combo Card kit x 20 tests + PC)	NW882001VC	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Crypto-Giardia (Blister kit x 40 tests)	KG740301V	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Crypto-Giardia (Blister kit x 40 tests + PC)	KG740301VC	15.70.05.90	02/06/2020 RPS/1176/2020
CerTest Entamoeba (Card kit x 20 tests)	EH820001V	15.70.05.90	18/09/2013 RPS/866/2013
CerTest Entamoeba (Card kit x 20 tests + PC)	EH820001VC	15.70.05.90	18/09/2013 RPS/866/2013
CerTest Crypto+Giardia+Entamoeba (Triple Card kit x 20 tests)	NE872001V	15.70.05.90	24/09/2013 RPS/872/2013
CerTest Crypto+Giardia+Entamoeba (Triple Card kit x 20 tests + PC)	NE872001VC	15.70.05.90	24/09/2013 RPS/872/2013
CerTest Strep A (Card kit x 20 tests+ PC)	T820201PC	15.70.01.03	02/06/2020 RPS/1176/2020
CerTest Strep A (Blister kit x 20 tests+ PC)	T720201PC	15.70.01.03	02/06/2020 RPS/1176/2020
CerTest RSV (Card kit x 20 tests+ PC)	RV820001PC	15.70.90.02	02/06/2020 RPS/1176/2020
CerTest RSV (Blister kit x 20 tests+ PC)	RV720001PC	15.70.90.02	02/06/2020 RPS/1176/2020
CerTest Adenovirus Resp. (Card kit x 20 tests+ PC)	AP820001PC	15.70.90.90	RPS/1176/2020
CerTest Adenovirus Resp. (Blister kit x 20 tests+ PC)	AP720001PC	15.70.90.90	RPS/1176/2020
CerTest RSV+Adenovirus Resp. (Combo Card kit x 20 tests+ PC)	VR882001PC	15.70.90.90	04/06/2020 RPS/1206/2020
CerTest RSV-Adenovirus Resp. (Blister kit x 20 tests+ PC)	VR720301PC	15.70.90.90	04/06/2020 RPS/1206/2020
CerTest Influenza A (Card kit x 20 tests+ PC)	Y820001PC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Influenza A (Blister kit x 20 tests+ PC)	Y720001PC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Influenza A+B (Combo Card kit x 20 tests+ PC)	Z882001PC	15.70.90.90	02/06/2020 RPS/1176/2020
CerTest Influenza A+B (Blister kit x 20 tests+ PC)	ZR720301PC	15.70.90.90	02/06/2020 RPS/1176/2020



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CerTest Influenza A+B+RSV (Triple Card kit x 20 tests)	ZS872001P	15.70.90.04.00 & 15.70.90.02.00	15/12/2016 RPS/637/2016
CerTest Influenza A+B+RSV (Triple Card kit x 20 tests+ PC)	ZS872001PC	15.70.90.04.00 & 15.70.90.02.00	15/12/2016 RPS/637/2016
CerTest Influenza A+B+RSV+Adeno Resp. (Quad Card kit x 20 tests)	ZV862001P	15.04.08.04 & 15.70.90.02, 15.04.80.01	23/05/2012 RPS/512/2012
CerTest Influenza A+B+RSV+Adeno Resp. (Quad Card kit x 20 tests + PC)	ZV862001PC	15.04.08.04 & 15.70.90.02, 15.04.80.01	23/05/2012 RPS/512/2012
CerTest Legionella (Card kit x 20 Test+ PC+NC)	LP820201PC	15.70.01.08	04/06/2020 RPS/1208/2020
CerTest Legionella (Blister kit x 20 Test+ PC+NC)	LP720201PC	15.70.01.08	04/06/2020 RPS/1208/2020
CerTest S. pneumoniae (Card kit x 20 Test+ PC+NC)	SN820201PC	15.70.01.09	04/06/2020 RPS/1208/2020
CerTest S. pneumoniae (Blister kit x 20 Test+ PC+NC)	SN720201PC	15.70.01.09	04/06/2020 RPS/1208/2020
CerTest S. pneumoniae+Legionella (Combo Card kit x 20 Test+ PC+NC)	NL882201PC	15.70.01.09.00 & 15.70.01.08.00	22/12/2016 RPS/647/2016

MANUFACTURER		
Name of company	Address	Representative
CERTEST BIOTEC S.L.	POL. INDUSTRIAL RIO GALLEG0 II, CALLE J, Nº 1, 50840, SAN MATEO DE GALLEG0, ZARAGOZA (SPAIN)	Nelson Gonçalves Fernandes
CONFORMITY ASSESSMENT		
Device classification	Route of compliance	
Other IVD-Self declaration	Anexo III of IVDD 98/79/CE Council Directive	

CerTest Biotec S.L. declares that the above mentioned products covered by this declaration conform with the Essential Requirements of EC Directive 98/79/EC (annex I).